

II. REMARKS

Preliminary Remarks

The applicants would like to thank the examiner for the interview of August 8, 2005.

Upon entry of the this Amendment, claims 148, 150, 175, and 177 to 190 are pending, of which claims 148, 175, and 179 are independent. Claims 148, 150, 175, and 179 to 181 are amended and claims 149, 151, and 191 are canceled. Support for the claim amendments may be found in the specification as filed (see, for example, page 1, lines 15 to 27, page 17, line 3 to 5, and page 18, line 30 to page 19, line2). Therefore, the applicants believe that no new matter is added.

This response is filed within the shortened statutory period for response, no fee due, and is accompanied by a Request for Continued Examination (RCE) and a check for the required fee. The applicants respectfully request reconsideration and allowance of the present application.

Patentability Remarks

Rejection under 35 U.S.C. §112 –

Claims 148 to 151, 175, and 177 to 191 were rejected under 35 U.S.C. §112, first paragraph, for scope of enablement. The applicants respectfully traverse.

Claims 149, 151, and 191 are canceled. As amended, claims 148, 150, 175, and 177 to 190 are directed to, *inter alia*, a method for the treatment of an inflammatory disease or disorder in a subject by administering a composition comprising specific boswellic acids.

The applicants respectfully submit that the specification as filed fully enables claims 148, 150, 175, and 177 to 190 per the requirements of 35 U.S.C. §112, first paragraph, and respectfully request withdrawal of this rejection.

Rejections under 35 U.S.C. §103 –

Claims 148 to 151, 175, and 177 to 191 were rejected under 35 U.S.C. §103(a) as being unpatentable over Koji *et al.* (JP 04-288095, also referred to by the examiner as Nagasawa *et al.*). The applicants respectfully traverse.

Claims 149, 151, and 191 are canceled. As amended, claims 148, 150, 175, and 177 to 190 are directed to, *inter alia*, a method for the treatment of an inflammatory disease or disorder in a subject by administering a composition comprising four specific boswellic acids, namely (1) β -boswellic acid, (2) acetyl- β -boswellic acid, (3) 11-keto- β -boswellic acid, and (4) acetyl-11-keto- β -boswellic acid.

While Koji *et al.* generically describe four boswellic acids, they explicitly remove two of the four boswellic acids, leaving only two. In particular, Koji *et al.* hydrolyze the two acetyl boswellic (acetyl- β -boswellic acid and acetyl-11-keto- β -boswellic acid), using (generally) alkaline hydrolysis, to remove the acetyl group (see paragraph [0015], Specific Examples 2, 3, 5, 7 (which uses acid hydrolysis)). In other words, at best the compositions of Koji *et al.* contain only β -boswellic acid and 11-keto- β -boswellic acid.

In contrast, the claimed invention requires at least one boswellic acid to contain the acetyl group. Therefore, Koji *et al.* do not fairly teach or suggest the claimed invention to one of ordinary skill in the art. Indeed, Koji *et al.* teach away from the present invention by explicitly hydrolyzing the acetyl groups off the boswellic acids.

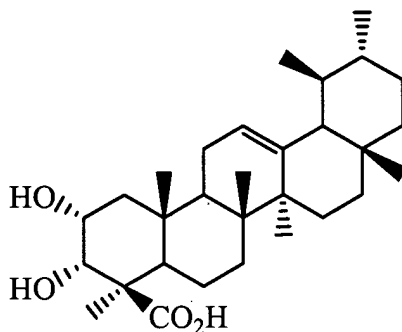
In conclusion, the applicants respectfully submit that amended, claims 148, 150, 175, and 177 to 190 are not unpatentable under 35 U.S.C. §103(a) over Koji *et al.* and respectfully request withdrawal of this rejection.

Claims 148 to 151, 175, and 177 to 191 were rejected under 35 U.S.C. §103(a) as being unpatentable over Taneja *et al.* (EP 0 755 940). The applicants respectfully traverse.

Once again, claims 149, 151, and 191 are canceled. As amended, claims 148, 150, 177, and 178 are directed to, *inter alia*, a method for the treatment of an inflammatory disease or disorder in a subject by administering a composition comprising four specific boswellic acids, namely (1) β -boswellic acid, (2) acetyl- β -boswellic acid, (3) 11-keto- β -boswellic acid, and (4) acetyl-11-keto- β -boswellic acid. The boswellic acids

administered are limited to combinations of these four, though the composition itself can contain other non-boswellic acid components. As amended, the boswellic acids in the composition of claim 175 consists essentially of acetyl-11-keto- β -boswellic acid. Finally, as amended, the composition of claims 179 to 190 comprise three specific boswellic acids.

Taneja *et al.* describe six boswellic acids and their invention requires all six (see page 4, lines 30 to 35). In particular, their invention requires a “new” boswellic acid, which they refer to as Formula VI and which has the structure shown next:



As amended, this compound cannot form a part of the claimed invention. There is no teaching or suggestion in Taneja *et al.* that any one of the six boswellic acids can be removed. Indeed, they state, “it is our novel finding according to the present invention that the fraction containing the mixture of boswellic acids of the formulae 1 to 6” synergistically shows the desired effects (page 4, lines 32 to 33, emphasis added). Taneja *et al.* are further specifically interested in isolating the boswellic acid of Formula VI (page 4, lines 36 to 58).

The applicants respectfully submit that Taneja *et al.* neither teaches, nor fairly suggests, the claimed invention, in which the boswellic acids component is limited to four specific boswellic acids, none of which is Formula VI. Removal of Formula VI (and Formula V) from the composition of Taneja *et al.* to get to the claimed invention would render Taneja *et al.* unsatisfactory for its intended purpose (see M.P.E.P. §2143.01). Therefore, the applicants respectfully submit that claims 148, 150, 175, and 177 to 190 are not unpatentable under 35 U.S.C. §103(a) over Taneja *et al.* and respectfully request withdrawal of this rejection.


III. CONCLUSION

In view of the amendments and remarks above, the applicants respectfully submit that this application is in condition for allowance and request favorable action thereon.

In the event this response is not timely filed, the applicants hereby petition for an appropriate extension of time. The fee for this extension, along with any additional fees required with respect to this response, may be charged to Deposit Account No. 01-2300, referencing Attorney Docket No. 108064-00049.

Respectfully submitted,

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